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Newly Adopted and Amended Guidance Documents

During the Virginia Board of Pharmacy meeting held on March 29, 2007, the Board moved to adopt or amend several guidance documents in an effort to provide licensees with assistance on several matters. The three guidance documents that most directly affect licensees are 110-12, 110-15, and 110-35. A summary of these guidance documents is provided below. To read the complete minutes associated with the March Board meeting click on www.dhp.virginia.gov/pharmacy/pharmacy_calendar.htm.

Guidance Document 110-12

The use of compliance packaging that is composed of a series of individual containers or pockets labeled with the specific date and time when the contents of that container are to be taken, and which may contain more than one different drug, must comply with United States Pharmacopeia (USP)-National Formulary standards for customized patient medication packages. Additionally, USP requires that if the packaging allows for the separation of the individual containers, that the labels for each individual container be labeled with the identity of each of the drug products contained within. Recently, however, the Board was asked to offer guidance as to what information the patient must be given if the desire was to provide the patient with only a short supply of these minimally labeled individual containers, instead of the entire compliance package, when leaving a facility for a period of time.

Board advice on this matter is captured in guidance document 110-12. It states that the individual containers must be labeled as described above, and that other documentation that contains the complete information required for labeling be packaged with the individual containers. Such documentation could be a copy of the main compliance package label, a medication administration record containing all required information, or other document that contains all required information.

Refer to www.dhp.virginia.gov/pharmacy/guidelines/110-12%20Compliance%20Packaging%20guidance.doc for the entire guidance document.

Guidance Document 110-15: Substitution of Albuterol CFC with Albuterol HFA

Effective December 31, 2008, the US Food and Drug Administration (FDA), is removing the “essential-use” exemption for albuterol chlorofluorocarbon (CFC) metered-dose inhalers (MDI), after which date these products may no longer be manufactured or sold. As a result, pharmacies are already facing a supply shortage of albuterol CFC and will need to begin switching patients to the newer, non-ozone depleting hydrofluoroalkane (HFA) formulation. Concern has been raised about whether a pharmacist must call a prescriber for permission to switch a patient from albuterol CFC to albuterol HFA since the two items are not technically equivalent and are not rated as therapeutically equivalent in the FDA’s “Orange Book.”

In order to prevent confusion and ease the transition, the Board has issued a new guidance document, 110-15. This document states that a pharmacist need not call a prescriber for permission to switch a patient from CFC to HFA provided:

1. the prescriber did not specify the CFC formulation on the prescription; and
2. the pharmacist counsels the patient about the product change to include the reason for the change and differences that the patient may experience.

The complete guidance document may be found at www.dhp.virginia.gov/pharmacy/guidelines/110-15Guidance%20on%20dispensing%20albuterol%20HFA%20for%20previously%20dispensed%20CFC%20inhalers%203-07.doc

Additional information about the FDA actions may be found at www.fda.gov/cder/mdi/mdifaqs.htm.

Guidance Document 110-35

Generally, community pharmacists are constrained to filling prescriptions under the “one prescription per blank” law (§54.1-3408.01). Recently though, discharge medication orders written for patients on hospital chart order forms have been showing up at community pharmacies and pharmacists have questioned whether they can use this chart order for dispensing from an outpatient setting since the chart orders usually have multiple prescription orders on

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FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at www.fda.gov/medwatch/report/hcp.htm. Reports can also be made by phone at 1-800/FDA-1088.

Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.

During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger

than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.

Changes in Medication Appearance Should Prompt Investigation



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

As the number of generic products continues to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.



After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**[®] (letrozole) but instead received the estrogen replacement product **femhrt**[®] (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

FDA Launches CDERLearn Educational Tutorial on MedWatch

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at www.connectlive.com/events/fdamedwatch. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at www.fda.gov/cder/learn/CDER-Learn/default.htm.

ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at www.buprenorphine.samhsa.gov.

Deadline Approaches for Pharmacists to Use NPI Numbers

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require pharmacists to begin using the National Provider Identifier (NPI) by May 23, 2007. These provisions are intended to improve the efficiency and effectiveness of the electronic transmission of health information. Pharmacists can apply online or print an application for an NPI at <https://nppes.cms.hhs.gov>.

one form. The Board reviewed the law and determined that the law did not preclude the dispensing of prescriptions by a community pharmacy provided certain conditions were met as follows:

- ◆ The chart order was written for a patient while the patient was in a hospital or long term care facility.
- ◆ The pharmacist has all information necessary to constitute a valid outpatient prescription.
- ◆ The pharmacist in an outpatient setting must have direction, either written or obtained verbally, that the chart order is actually intended to be outpatient or discharge prescription orders, and not merely a listing of drugs the patient was taking while an inpatient.
- ◆ The orders include some direction as to quantity to be dispensed, or duration of the order and directions for use by which the pharmacist can calculate the authorized quantity.

This new interpretation has been added to existing guidance document 110-35 under the subsection entitled "Written Prescriptions." To review the entire document click on www.dhp.virginia.gov/pharmacy/guidelines/110-35%20Requirements%20for%20prescriptions.doc.

Life of a Prescription When the Prescriber Is No Longer In Practice

Questions arise as to whether a pharmacist may refill prescriptions with authorized refills when the prescriber is no longer in practice. The reason for cessation of practice may include, but is not limited to, relocation, retirement, death, suspension or revocation of license, and long-term illness. While there is nothing in the Drug Control Act that specifically addresses this issue, the Board does capture advice on this subject within guidance document 110-25, which was adopted on October 5, 1999.

In brief, the Board determined that in the absence of any specific instructions from the original prescriber or a subsequent practitioner assuming medical care of the patient, the validity of refilling these prescriptions should be left to the professional judgment of the pharmacist. Additionally, the document states that each prescription should be evaluated on an individual basis to determine which course of action would be in the best interest of the patient. Lastly, it states that each patient should be encouraged to establish a relationship with a new medical practitioner as soon as possible and have that practitioner write new prescriptions for any required drugs.

For a complete viewing of guidance document 110-25 click on www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

Remodeling?

Pharmacists frequently have questions as to whether a planned renovation of an existing prescription department, or upgrade of an alarm system, requires notification to the Board, inspection, and approval. A remodel of a pharmacy prescription department is defined in regulation as a structural change to an existing prescription department, or a change to a previously approved security system. For example, the installation of additional motion sensors or of a pull-down gate that encloses the prescription department would be considered a remodel, thus requiring the submission of the application and a Board inspection. Adding cabinetry or equipment that may

interfere with sensors for an already approved alarm system would be considered a remodel. Any changes to the locks on the doors or gates enclosing the prescription department would probably be a remodel, unless it is simply to replace a broken lock. Changing the carpet, however, would probably not constitute a remodel, as it is not a structural change. The installation of video cameras or adding a contact sensor to a door probably would not constitute a remodel since neither of these items is required for a prescription department unless the equipment somehow interfered with the existing alarm equipment. If there is any question as to whether a change would be considered a remodel, pharmacists should contact the Board office for direction.

If the change does constitute a remodel, the owner or pharmacist-in-charge (PIC) must submit an application for a pharmacy permit and check the box at the top of the form marked "remodel." Plans should not be submitted to the Board office; however, the PIC is responsible for ensuring that the security of the drugs is never compromised during the remodeling. For new pharmacies or the change of an existing pharmacy to a different location, drugs are not permitted to be stocked until the location has been inspected and approved. This is not the case with a remodel of an existing prescription department because drugs have already been permitted to be stocked in the area, unless the remodel involves the expansion of the prescription department. During an expansion, drugs must not be located or stored in the expanded area until inspected by the Board. Once the Board has received the application and the remodeling is complete, an inspector will schedule an inspection. The application form should indicate a desired date for inspection; however, inspectors do require a 14-day notice for scheduling purposes, and frequently these dates have to be changed because of construction delays or other reasons. However, the application should be submitted and the inspection date planned to accommodate the earliest possible inspection after the remodeling has been completed. The pharmacy is responsible for immediately correcting any deficiencies identified during the inspection caused by the remodeling.

If a pharmacy fails to notify the Board of a remodel and this failure to notify is identified during a subsequent routine inspection, the pharmacy will face possible disciplinary action. Guidance document 110-26 recommends a \$250 monetary penalty for this deficiency in addition to immediately correcting anything not in compliance. Additionally, the owner may be charged a reinspection fee if warranted.

The Application for a Pharmacy Permit may be accessed at www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm and guidance document 110-26 may be found at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.